Complete Summary

GUIDELINE TITLE

Diagnosis and management of adults with chronic kidney disease.

BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Diagnosis and management of adults with chronic kidney disease. Southfield (MI): Michigan Quality Improvement Consortium; 2008 Nov. 1 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Michigan Quality Improvement Consortium. Diagnosis and management of adults with chronic kidney disease. Southfield (MI): Michigan Quality Improvement Consortium; 2006 Nov. 1 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Chronic kidney disease (CKD)

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nephrology

INTENDED USERS

Advanced Practice Nurses
Health Plans
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To achieve significant, measurable improvements in the diagnosis and aggressive management of chronic kidney disease (CKD) through the development and implementation of common evidence-based clinical practice guidelines
- To design concise guidelines that are focused on key management components of chronic kidney disease to improve outcomes

TARGET POPULATION

- Adults at increased risk for chronic kidney disease (CKD)
- Adults with chronic kidney disease

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis

Assessment of markers of kidney damage (e.g., blood pressure measurement, estimated glomerular filtration rate [GFR], protein-to creatinine or albumin-to-creatinine ratio, urinalysis, fasting lipid profile, electrolytes, blood urea nitrogen [BUN])

Management/Treatment

1. Evaluation and management of comorbid conditions such as diabetes, hypertension, urinary tract obstruction, cardiovascular disease
2. Review of medications for dose adjustment, drug interactions, adverse effects, and therapeutic levels
3. Patient education on lifestyle changes such as dietary sodium restrictions, weight maintenance, weight loss, exercise, alcohol intake, smoking cessation
4. Development of clinical action plan for each patient based on disease stage
5. Incorporation of self-management behaviors into treatment plan at all stages
6. Management according to kidney disease stage
    - Monitoring GFR
    - Smoking cessation and maintenance of blood pressure and lipid goals
    - Nephrology/renal dietician referral or consult
    - Aspirin therapy
    - Angiotensin-converting enzyme (ACE) inhibitor/angiotensin receptor blocker therapy
    - Suppression of parathyroid hormone levels with vitamin D
    - Phosphorus lowering treatment
    - Correction of iron deficiency
    - Erythropoiesis stimulating agent (ESA)
    - Vaccine updates
    - CKD education class
    - Renal replacement therapy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Michigan Quality Improvement Consortium (MQIC) project leader conducts a search of current literature in support of the guideline topic. Computer database searches are used to identify published studies, existing protocols, and/or national guidelines on the selected topic developed by organizations such as the American Diabetes Association, American Heart Association, American Academy of Pediatrics, etc. If available, clinical practice guidelines from participating MQIC health plans and Michigan health systems are also used to develop a framework for the new guideline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational studies
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Using information obtained from literature searches and available health plan guidelines on the designated topic, the Michigan Quality Improvement Consortium (MQIC) project leader prepares a draft guideline to be reviewed by the medical directors' committee at one of their scheduled meetings. Priority is given to recommendations with [A] and [B] levels of evidence (see "Rating Scheme for the Strength of the Evidence" field).

The initial draft guideline is reviewed, evaluated, and revised by the committee resulting in draft two of the guideline. Additionally, the Michigan Academy of Family Physicians participates in guideline development at the onset of the process and throughout the guideline development procedure. The MQIC guideline feedback form and draft two of the guideline are distributed to the medical directors, as well as the MQIC measurement and implementation group members, for review and comments. Feedback from members is collected by the MQIC project leader and prepared for review by the medical directors' committee at their next scheduled meeting. The review, evaluation, and revision process with several iterations of the guideline may be repeated over several meetings before consensus is reached on a final draft guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When consensus is reached on the final draft guideline, the medical directors approve the guideline for external distribution to practitioners with review and comments requested via the Michigan Quality Improvement Consortium (MQIC) health plans (project leader distributes final draft to medical directors' committee, measurement and implementation groups to solicit feedback).

The MQIC project leader also forwards the approved guideline draft to appropriate state medical specialty societies for their input. After all feedback is received from external reviews, it is presented for discussion at the next scheduled committee meeting. Based on feedback, subsequent guideline review, evaluation, and revision may be required prior to final guideline approval.

The MQIC Medical Directors approved this updated guideline in November 2008.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence grades (A-D) are provided for the most significant recommendations and are defined at the end of the "Major Recommendations" field.

Screening and Diagnosis

All Adults at Increased Risk for Chronic Kidney Disease (CKD)

For patients at increased risk for CKD (e.g., diabetes, hypertension, family history of kidney failure, kidney stones, etc.) assess for markers of kidney damage:

- Measure blood pressure **[A]**
- Obtain estimated glomerular filtration rate (GFR)[1] **(serum creatinine levels should not be used as sole means to assess renal function)**
- Protein-to-creatinine ratio **or** albumin-to-creatinine ratio (first morning or random spot urine specimen)

- Urinalysis, fasting lipid profile, electrolytes, blood urea nitrogen (BUN)

Frequency

- Semi-annual blood pressure monitoring; more frequent monitoring if indicated
- Monitor GFR every 1–2 years

[1]If not calculated by lab, refer to the National Kidney Foundation website for GFR calculator (**http://www.kidney.org/professionals/tools/**)

Risk Factor Management and Patient Education

All Adults at Increased Risk for CKD

- Evaluation and management of comorbid conditions (e.g., diabetes, hypertension, urinary tract obstruction, cardiovascular disease)[2]
- Review medications for dose adjustment, drug interactions, adverse effects, therapeutic levels
- Educate on therapeutic lifestyle changes: dietary sodium intake < 2.4 grams/day (g/d) recommended for patients with CKD and hypertension **[A]**, weight maintenance if body mass index (BMI) <25, weight loss if BMI ≥ 25, exercise and physical activity, moderation of alcohol intake, smoking cessation

Frequency

At each routine health exam

[2]Reference MQIC guidelines on diabetes, hypertension, hyperlipidemia and obesity (http://www.mqic.org).

Adults with CKD

<u>All of the above plus:</u>

- Develop clinical action plan for each patient, based on disease stage as defined by the National Kidney Foundation, Kidney Disease Outcomes Quality Initiative (K/DOQI) **[B]**
- Incorporate self-management behaviors into treatment plan at all stages of CKD **[B]**

Frequency

At each routine health exam

Core Principles of Treatment

Adults with CKD

- **Stage 1 (GFR >90)**: Monitor GFR annually, smoking cessation, consider aspirin (ASA), consider angiotensin converting enzyme (ACE) and/or angiotensin receptor blocker (ARB) therapy, blood pressure (BP) goal <130/80, low density lipoprotein-cholesterol (LDL-C) goal <100
- **Stage 2 (GFR 60–89)**: Nephrology referral if GFR decline > 4mL/min/yr, maintain BP and lipid goals as above
- **Stage 3 (GFR 30–59)**: Consult Nephrologist and Renal Dietician; Suppress parathyroid hormone (PTH) with vitamin D to level appropriate for CKD stage; Phosphorus lowering treatment if > 4.6 mg/dl; Correct iron deficiency before start of erythropoiesis stimulating agent (ESA); ESA if hemoglobin (Hgb) (hematocrit [Hct]) <10 (30%); renal-specific vitamins; Update vaccines: hepatitis B virus (HBV), influenza, tetanus/diphtheria acellular pertussis vaccine (Tdap) and Pneumovax
- **Stage 4 (GFR 15–29)**: Nephrology and vascular access surgery referrals, ESA if Hgb <10 g/dL, Optimize Ca x P product to < 55 with specific agents, update vaccines as indicated, CKD education classes
- **Stage 5 (GFR <15)**: Renal replacement therapy

Frequency

As indicated

Definitions:

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational studies
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for the most significant recommendations (see "Major Recommendations" field).

This guideline is based on the Henry Ford Health System, Divisions of Nephrology and Hypertension and General Internal Medicine Chronic Kidney Disease (CKD) Clinical Practice Recommendations for Primary Care Physicians and Healthcare Providers, Edition 5.0 (www.ghsrenal.com).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Through a collaborative approach to developing and implementing common clinical practice guidelines and performance measures for diagnosis and aggressive management of chronic kidney disease (CKD), Michigan health plans will achieve consistent delivery of evidence-based services and better health outcomes. This approach also will augment the practice environment for physicians by reducing the administrative burdens imposed by compliance with diverse health plan guidelines and associated requirements.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline lists core management steps. Individual patient considerations and advances in medical science may supersede or modify these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Approved Michigan Quality Improvement Consortium (MQIC) guidelines are disseminated through email, U.S. mail, and websites.

The MQIC project leader prepares approved guidelines for distribution. Portable Document Format (PDF) versions of the guidelines are used for distribution.

The MQIC project leader distributes approved guidelines to MQIC membership via email.

The MQIC project leader submits request to website vendor to post approved guidelines to MQIC website (www.mqic.org/).

The MQIC project leader completes a statewide mailing of the comprehensive set of approved guidelines and educational tools annually. The guidelines and tools are distributed in February of each year to physicians in the following medical specialties:

- Family practice
- General practice
- Internal medicine
- Other specialists for which the guideline is applicable (e.g., endocrinologists, allergists, pediatricians, cardiologists, etc.)

The statewide mailing list is derived from the Blue Cross Blue Shield of Michigan (BCBSM) provider database. Approximately 95% of the state's M.D.s and 96% of the state's D.O.s are included in the database.

The MQIC project leader submits request to the National Guidelines Clearinghouse (NGC) to post approved guidelines to NGC website (www.guideline.gov).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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DATE RELEASED

2006 Nov (revised 2008 Nov)

GUIDELINE DEVELOPER(S)

Michigan Quality Improvement Consortium - Professional Association

SOURCE(S) OF FUNDING

Michigan Quality Improvement Consortium

GUIDELINE COMMITTEE

Michigan Quality Improvement Consortium Medical Director's Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community Health and Michigan Peer Review Organization

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Standard disclosure is requested from all individuals participating in the Michigan Quality Improvement Consortium (MQIC) guideline development process, including those parties who are solicited for guideline feedback (e.g., health plans, medical specialty societies). Additionally, members of the MQIC Medical Directors' Committee are asked to disclose all commercial relationships as well.

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Michigan Quality Improvement Consortium Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 13, 2007. The information was verified by the guideline developer on July 16, 2007. This summary was updated by ECRI Institute on March 21, 2008 following the FDA advisory on Erythropoiesis Stimulating Agents. This summary was updated by ECRI Institute on August 15, 2008 following the U.S. Food and Drug Administration advisory on Erythropoiesis Stimulating Agents (ESAs). This summary was updated by ECRI Institute on June 8, 2009. The updated information was verified by the guideline developer on June 30, 2009.

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Readers with questions regarding guideline content are directed to contact the guideline developer.

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